MAXIMUM CONSTITUENT LEVELS IN THE EEC AND THE LOW-YIELD CIGARETTE: ARGUMENTATION

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I. <u>INTRODUCTION</u>

Tobacco smoke is a highly complex mixture containing thousands of constituents. Although tobacco smoke constituents are among the most heavily researched substances in the world, no constituent as found in cigarette smoke (including "tar") has been scientifically proven to cause cancer or any other human disease. Nor has any health benefit from switching to low "tar" cigarettes been scientifically established. Thus, legislation establishing maximum levels for smoke constituents is unsupportable on public health grounds. Nonetheless, a proposed European Community Council Directive calls for the prohibition of the sale of cigarettes with "tar" yields of more than 15 milligrams (mg) by the end of 1992 and of more than 12 mg by the end of 1995.

Proposals to mandate maximum "tar" levels will <u>not</u> bring about the result envisioned by such proposals' sponsors -- a

Philip Morris does not represent low "tar" and nicotine 1. cigarettes as being "safer." Low "tar" and nicotine cigarettes are on the market in response to consumer demand, which has increased in recent years. Because of these changes in consumer preferences, Philip Morris has modified its production and shifted its emphasis in advertising. current popularity of some of Philip Morris' newer brands is consistent with trends in consumer preference for many Consumer tastes are changing, as demonstrated by the growing demand for "lighter" products such as low-calorie beers, sugar-free soft drinks, low fat foods and the like. In addition, much media and public attention has been given the views of some scientists concerning these newer cigarettes. As a result, it is entirely possible that some smokers have been influenced by this publicity.

general reduction in the amount of "tar" to which smokers are exposed. Rather, the imposition of limits will reduce product acceptability leading to unforseen changes in consumer smoking habits in ways completely outside the control of governmental authorities. Instead of switching to cigarettes with lower "tar" and nicotine levels, many smokers, perhaps a majority, will change how or what they smoke in a manner which would not be approved by those who contend that smoking is injurious to health. Smokers will roll their own cigarettes with or without filters using greater or lesser amounts of tobacco, they will purchase contraband cigarettes on the "black market," they will break off the filter of a manufactured cigarette, they will switch to cigars or pipes, they will take more or deeper puffs from manufactured cigarettes or they will perhaps smoke the cigarette down to the very end.

Experience has shown that the probability that smokers of higher "tar" cigarettes will switch to hand-rolling their own cigarettes (or to contraband cigarettes) after their product has been banned is very high. Such a switch will put manufactured cigarettes at a considerable competitive disadvantage since, in the absence of an adequate measurement method, no maximum yield can be set for hand-rolled cigarettes. It is also undesirable from a health policy point of view and may even be considered "counterproductive" by anti-smoking advocates because "tar" levels

of hand-rolled cigarettes are believed to be far higher than those of manufactured cigarettes.

Enacting proposals to establish maximum constituent levels will create a number of practical problems, as well. If maximum levels of one or more constituents are to be set, standardized testing procedures would need to be established to determine the levels of such substances in cigarette smoke. Countries which have adopted such proposals have had to develop testing procedures which require elaborate, expensive equipment and trained personnel. Who will assume this expense -- the Government, the cigarette industry, or the smoker? How will such tests allow for the many variations between tobaccos that are influenced by such factors as the type of fertilizer used and the weather conditions during the growing season? There are also many practical problems developing testing and measuring procedures which attempt to duplicate the way humans smoke. No two people smoke the same way, and no one smoker smokes the same way all the time. Some smokers take long puffs; others take short ones. Some put their cigarettes down in ashtrays for long periods; others constantly keep them in their mouth. When a smoker is excited, he may take more puffs; when he is relaxed, he may take fewer puffs. In contrast, the "tar" levels printed on cigarette packets are determined by mechanically smoking cigarettes under defined laboratory conditions. These conditions do not and cannot duplicate the way in which an individual smokes, nor do they give the individual smoker a reasonably accurate idea of the constituent levels of the cigarette he is smoking. Even if these initial difficulties can be overcome, the reliability of the test ratings is questionable. Any effort to establish uniform constituent levels can only be approximate since differences of as much as one mg may not be detected during the test procedures. Thus, the consumer receives inaccurate, misleading information.

The enactment of maximum constituent levels also will create economic and political problems for the Member States. For example, it is likely to lead to the development of a criminal element specializing in smuggling cigarettes from areas which do not impose such levels. Additionally, the agricultural sector of the economies of many States will be severely disrupted.

II. THE "SCIENCE OF TOBACCO" DOES NOT SUPPORT THE IMPOSITION OF MAXIMUM CONSTITUENT LEVELS

Anti-smoking advocates frequently assert that nicotine or carbon monoxide (CO) cause disease in humans. The same is also said about "tar," even though it is a laboratory product and not an actual constituent of tobacco smoke. Over the years, much time and effort has been devoted to determining the identity of tobacco smoke constituents. This has proven difficult, however, and much remains to be learned about the structure and makeup of tobacco

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smoke and its effects, if any, on human health. Nonetheless, proposals have frequently been made to establish maximum levels of such substances in cigarette smoke, including the Commission of the European Communities proposal to set a maximum "tar" level for manufactured cigarettes. Such efforts are not supported by the available scientific data.

The significance of smoke constituents to human health is not yet understood. In addition, the smoking machines used to measure "tar," carbon monoxide and nicotine levels have little relationship to what humans experience when they smoke. As a consequence, "no ingredient (constituent) or group of ingredients (constituents) as found in tobacco smoke have been established as disease producing in smokers." (1) Nor has it been proven that a reduction in the levels of those substances will decrease any claimed harmful effects of cigarette smoke.

A. "Tar"

"Tar" is not actually in tobacco smoke, although the many inaccurate references to "tar" in smoke may have created that impression. "Tar" is actually a laboratory product obtained by collecting the particulate matter in tobacco smoke, either by passing cigarette smoke through a cold trap at extremely low temperatures or by using filters and a drying process. However, material

collected in this way does not duplicate what humans are exposed to when they smoke:

"[T]here is, at present, no available instrumentation permitting the separation and individual collection of the particulate and gas phases which duplicates the precise physicochemical conditions prevailing in cigarette smoke as it is inhaled." (2)

Despite its lack of relevance to smoking, laboratoryproduced "tar" has been used in animal experiments designed to
investigate the possible relationship between tobacco smoke and
cancer. In those experiments, "tar" was repeatedly painted on the
shaved backs or ears of test animals over prolonged periods of
time. These so-called skin-painting experiments have prompted a
great deal of interest, as the tumors which resulted have been
said to be evidence that tumors might develop in human lungs from
inhaling cigarette smoke.

The results of such animal experiments cannot and should not be extrapolated to the human situation. Even if the "tar" collected by the methods described above were present in cigarette smoke, the "tar" used in skin painting experiments is very different by the time it is studied in the laboratory. That is because after "tar" is collected, it continues to undergo chemical changes as long as it is stored. (3) The chemical and physical changes brought about in collecting "tar" and applying it to animals

undoubtedly produce biological results quite different from any that may occur during inhalation.

No less substantial are the differences in the "tar" collected from different brands at different times, differences which are not reflected in weight measurements of the "tar". In hearings before the United States Senate in 1976 during which many of these issues were discussed, an expert identified these differences:

"The so-called 'tars' are complex mixtures of condensed smoke ingredients. 'Tars' vary in composition with tobacco types and treatments and with conditions of combustion, collection and storage. Equal amounts of two different 'tars' can have vastly different biological effects in animal experiments." (4)

Despite such "vast" differences, the weight of the "tar" as expressed in milligrams is the only way in which "tar" yields of cigarettes are described.

Furthermore, as an experimental toxicologist explained at the 1976 hearings, even if an effect such as tumor production is observed in a particular species, that does not necessarily mean that it might "occur either quantitatively or qualitatively in man." (5) Skin painting experiments suffer from a number of additional weaknesses. For example, the concentrations of "tar" used in such experiments are extremely high. One researcher has

estimated the amounts utilized to be equivalent to an individual smoking over 100,000 cigarettes per day (6). Furthermore, the skin and ears of laboratory animals are not similar to human lung tissue. Animal skin lacks the intricate clearance mechanisms of the lungs, such as the mucus blanket which coats the lining of the major airways of the lung. Even the summary report of a study sponsored by the United States government utilizing skin painting techniques conceded that there is an "uncertain relationship between tumors resulting from mouse skin painted with condensate and human lung cancer." (7) Consequently, such experiments involve applying "the wrong material, in the wrong form, in the wrong concentration, to the wrong tissue of the wrong animal." (8)

It is misleading, therefore, to draw definitive conclusions about "tar" and human disease from skin painting studies. As a knowledgeable observer of research in this area has stated: "Bronchogenic carcinoma [lung cancer] has never been produced by tobacco or its products in any experimental animal despite the multiplicity of attempts." (9) All in all, the current state of scientific evidence concerning "tar" may be concisely summarized:

"Human beings do not smoke 'tar' and laboratory reports on 'tar' yields have not been established as significant to human health." (10)

B. <u>Nicotine</u>

Nicotine is a natural element of tobacco and, thus, is present in tobacco smoke. Nicotine has been described as having no known chronic or cumulative effects on human health. (11) The data on the nature of nicotine's relationship to human health is inconclusive at best, because, among other things, science cannot determine with any precision how much nicotine a smoker is exposed to. In fact, no correlation between the nicotine level of a cigarette or the number of cigarettes smoked and the smoker's actual nicotine intake has been established because of individual variations in puff rates, depth of inhalation, and body metabolism. (12)

Nonetheless, anti-smoking advocates blame nicotine for the development of heart disease. Yet no mechanism by which nicotine, or any other agent, is involved in heart disease has been demonstrated. Serious questions about what role, if any, nicotine plays have been raised as a result of autopsy findings of fatty deposits and other changes in the arteries of individuals who either have not smoked or could have smoked only briefly, such as infants, children, and young men killed in battle. (13)U.S. the 1983 Surgeon General's Report, which focused cardiovascular disease, concedes that "the evidence for and against

a primary role for nicotine in the development or acceleration of atherosclerosis is not conclusive." (14) That opinion was shared by a German researcher who has conducted research on the relationship between nicotine and the clogging of arteries. After reviewing the literature, he and his co-author concluded that "there is no established evidence which supports the hypothesis that nicotine has any influence on the development" of those changes. (15)

The role of nicotine in the development of heart disease posited by anti-smoking advocates is further undermined by two epidemiological (population) studies. In a study that dealt with myocardial infarction (heart attack), the authors reported finding — contrary to what they expected — that the nicotine and carbon monoxide levels of the cigarettes smoked by their subjects were not related to the risk of heart attack. (16)

The second study, chaired by a well-known British scientist opposed to cigarette smoking, examined the serum (blood) levels of cotinine, a nicotine metabolite, in male nonsmokers and smokers of cigarettes only, cigars only, and pipes only. The study determined that the mean cotinine level for pipe smokers was significantly higher than the levels for cigarette and cigar smokers. Since studies of pipe smokers generally have not reported an increased risk of coronary heart disease, the researchers

concluded that "nicotine is unlikely to be the major cause of the excess coronary heart disease mortality in cigarette smokers."

(17) After re-evaluating their methodology in response to antismoking criticism of their study, the researchers again concluded, "we can be reasonably confident that exposure to high systemic concentrations of nicotine is not a cause of the disease." Although the researchers quibbled with the result of their own study, arguing that their data "cannot completely exonerate" nicotine, they added that the data do "substantially reduce the weight of evidence suggesting that nicotine is a cause of coronary heart disease."

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Animal studies which purport to establish a causal role for nicotine in heart disease have been soundly criticized for their unrealistic and excessive test conditions. An American researcher who conducted animal studies on this subject has noted:

"There have been some studies that have exhibited minor or questionable changes with the use of 600 or more cigarettes a day in man. This is such a large number that I think man would find it difficult to find the time to smoke them." (19)

In contrast, animal studies using realistic doses of nicotine have "failed to initiate, exacerbate, or otherwise influence" the process leading to the clogging of arteries in test animals. (20) In one such study, which was funded by the United States government, male

beagle dogs fed a special diet to induce this process were exposed for two years to cigarette smoke containing low or high levels of nicotine and, in some cases, enriched with CO. According to the final report of the research laboratory which conducted the study, "the results of this study lent no support to the suggestion that cigarette smoking increases the rate of development" of this process. (21)

The foregoing authorities demonstrate the validity of one researcher's summary: "While many studies have been done in this field, none have established nicotine as contributing to the causation, aggravation or precipitation of any cardiovascular disease." (22)

C. Carbon Monoxide

Carbon monoxide (CO) is a tasteless, odorless, colorless gas produced by many natural and man-made sources, including automobile exhaust and industrial emissions. Burning cigarettes also produce carbon monoxide, but that amount has been described as "insignificant" compared to most other sources. (23) It is also naturally produced during body metabolism. Nonetheless, CO has received considerable attention in the scientific literature, usually in regard to cardiovascular disease (CVD). In a review of such literature, however, two public health specialists concluded

that "despite the large amount of literature available, the conclusions that can be drawn as to the role of CO in human CVD remain tentative and open to varying interpretations." (24) This conclusion is supported by a similar statement in the 1983 U.S. Surgeon General's Report, which focused on heart disease:

"Carbon monoxide is another major component of cigarette smoke for which there are some data supporting a possible atherogenic role; however, a review of recent literature on the role of carbon monoxide in arterial injury and atherogenesis leads to no consensus." (25)

The conclusion of another group which also reviewed the literature was more concise. The chairman of the American Heart Association Task Force on Environment and the Cardiovascular System reported that his group had concluded that the question of whether CO causes heart disease "remains unanswered even at the basic science level." (26)

To support their claims about the adverse health effects of CO, anti-smoking advocates have emphasized the results of certain animal studies, particularly those of a Danish group who exposed rabbits on a high cholesterol diet to large quantities of CO. The exposed rabbits reportedly developed vascular changes similar to early clogging of the arteries in humans. (27) However, when they attempted to replicate or duplicate those changes in a later series of experiments utilizing the same levels of CO but non-

cholesterol-fed rabbits, the researchers were unsuccessful in doing so.

Specialists who reviewed these and other studies have concluded that "there is no evidence" to support the suggestion that exposure to low or moderate levels of CO increases the rate of development of atherosclerotic disease in man. Indeed, they contend that "sufficient evidence is available" to support the conclusion that "CO is not of pathogenetic consequence in atherosclerotic disease." (28)

The foregoing authorities demonstrate that "tobacco science" does not support constituent level restrictions. One researcher who has tried to establish a causal link between smoking and disease concluded:

"We assume that it is the tar which causes lung cancer, but we do not know this for certain.

Until now, we have implicated nicotine in the development of cardiovascular diseases, but we cannot prove this.

The same is true for CO." (29)

Proposals to mandate maximum constituent levels lack a reliable scientific basis.

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Despite the lack of reliable scientific proof regarding the alleged health effects of "tar," nicotine and carbon monoxide, proposals -- such as the EC Council Directive -- have frequently been made to limit the levels of one or more of these substances. In addition, numerous governments, anti-smokers and anti-smoking groups and health associations have publicly encouraged smokers to switch to the so-called low-yield cigarettes by advocating constituent labeling, league tables, "tar-reduction" programs and maximum constituent levels. As a result, some smokers have been led to believe that smoking low "tar" cigarettes is preferable to smoking higher "tar" cigarettes. These proposals, however, are without scientific foundation. A British toxicologist has noted that scientific data to support such proposals are not available:

"The toxicologist who seeks an objective basis upon which to predict increased 'safety' or reduced 'hazard' for tobacco products lacks the necessary quantitative experimental or clinical evidence to enable him to approach this task on the basis of the toxicology of any specific constituents of tobacco or tobacco smoke." (30)

Governmental sanction of the low-yield cigarette suggests to consumers that a reliable scientific basis exists for switching to it. This is not true.

A. Studies on Low-Yield Cigarettes and Disease Risk

The wide-spread scientific disagreement regarding the significance of the available data on the low "tar" cigarette is reflected by the published opinions on this subject. These differences of opinion are highlighted in the 1981 U.S. Surgeon General's Report which focused on "the changing cigarette" and "the relative health effects of cigarettes with varying levels of 'tar' and nicotine." (31) In the report's preface, for example, a senior government official noted that over the years U.S. public health officials had gradually assumed a "more cautious" attitude toward the low-yield cigarette; the 1981 Report, he noted, "suggests an even more cautious approach to the issue." (32) These concerns are reflected in the report's conclusions and in the accompanying commentary by U.S. health officials. In her introductory remarks to the report, for example, the head of the U.S. Department of Health and Human Services (DHHS) stated:

"In preparing this report, the scientists and scientific agencies of this Department have reviewed all current scientific evidence and have concluded that the search for less hazardous cigarettes has not yielded a product which can be considered 'safe.'" (33)

Subsequent reports of the Surgeon General have reiterated those conclusions. The 1983 report on cardiovascular disease noted that "epidemiologic evidence concerning reduced tar and nicotine or filter cigarettes and their effect on CHD rates is conflicting.

No scientific evidence is available concerning the impact on CHD death rates of cigarettes with very low levels of tar and nicotine".

(34) The 1984 report which examines the relationship between chronic obstructive lung disease (COLD) and cigarette smoking also noted that "evidence is unavailable on the relative risks of developing COLD consequent to smoking cigarettes with the very low tar and nicotine yields of current and recently marketed brands."

(35) Most recently, the 1989 U.S. Surgeon General's Report concluded that "there is no clear evidence of substantial health benefits to consumers who switch to lower tar and nicotine cigarettes" as "there is no known safe level of tobacco product consumption." (36)

Other scientific groups who have reviewed the available data on the low-yield cigarette have also commented on its inconclusive nature. For example, a committee convened by an operating agency of the U.S. National Academy of Sciences to analyze the data on "reduced tar and nicotine cigarettes" concluded that "the evidence for switching to lower T/N cigarettes is doubtful." The committee report explained that "while some large-scale studies have suggested small gains in health due to using lower T/N (or filter rather than nonfilter) cigarettes, other population-wide studies do not support this view." (37) Similarly, participants in an international workshop held to consider the advisability of a governmental "lower-tar policy" concluded with

the following cautionary statement even as they encouraged the move toward lower "tar" yields:

"The public needs to be made aware of the uncertainties of the policy, particularly those arising from compensatory smoking, and also that the benefits of smoking lower-yield cigarettes can only be small compared with those of avoiding the smoking habit altogether." (38)

Furthermore, as already suggested, there is strong disagreement regarding the nature of the relationship between the low-yield cigarette and disease mortality. This disagreement stems from data collected from epidemiological (population) studies, clinical studies, autopsy reports and laboratory analyses. As to the population studies, a scientific committee studying "reduced tar and nicotine cigarettes" concluded, based on its analysis of available data on U.S. respiratory system cancer (RSC) mortality trends, that "it is not possible to credit lower T/N cigarettes up to 1975 with significantly improving" male RSC mortality. (39)

More recent studies examining the relationship between the low-yield cigarettes and disease rates continue to undermine the validity of the position of MCL advocates regarding the relative merits of low-yield cigarettes. For example, a review of four cross-sectional and five prospective studies regarding the evidence on the relationship between smoking low-yield cigarettes and COLD

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concluded that there was "none for an effect on mortality" from that disease. 2 (40)

B. Machine Measurements and Human Smoking Behavior

Technical and scientific uncertainties abound regarding the low-yield cigarette. These begin with the popular but unscientific notion that the exposure of smokers to various cigarette smoke constituents can be determined by laboratory analysis. However, as researchers have pointed out, such procedures

^{2.} Autopsy studies have also prompted criticism of the "conventional wisdom" about the health effects of the low-yield ciga-In a well-publicized study published in 1979, an American pathologist and his co-authors compared specimens of bronchial epithelium obtained during the autopsies of about 150 regular cigarette smokers who died during the period 1955 to 1960 to those from about 180 smokers who died during 1970-In their study, they reported finding changes which they regarded as precancerous far more frequently in the smokers who died in the Fifties than those in the Seventies. They contended that this reduction in the latter group could be attributed to the decline in "tar" and nicotine levels over that same period of time. The article does not explain, why invasive or very early bronchial carcinoma was however, actually found more frequently in sections taken from low "tar"/nicotine smokers than from high "tar"/nicotine smokers, although the number involved was very small. (42)Nor did the researchers explain why their overall conclusions are inconsistent with observed trends in lung cancer mortality rates. Lung cancer mortality rates should have fallen sharply in recent years, if their theory is correct. However, this is clearly not the case. The significance of these findings has been challenged for other reasons as well. For example, it has been reported that these same changes occur in nonsmokers, (43) and one of the study's co-authors has conceded that they have been unable to show that these changes actually progress to lung cancer. (44)

cannot realistically imitate the way people smoke. There are simply too many uncontrolled factors which vary considerably among smokers and even in individual smokers, including the number of cigarettes smoked per day, the frequency of puffs, the depth and degree of inhalation and the length that each cigarette is smoked (i.e., the butt length). (45)In contrast, "tar," nicotine, and CO levels appearing on packets and in advertisements are obtained by smoking cigarettes mechanically under a set of defined laboratory conditions. Although such listings can provide a basis of comparison between brands or types of cigarettes, they do not accurately reflect the delivery of smoke to any individual smoker. This situation was succinctly summarized in a recent publication on this subject:

"In the United States, cigarette yields are determined by the Federal Trade Commission (FTC) according to standard procedures similar to methods used in other countries. The results of such tests do not represent the full behavioral range of individual smokers; as the FTC itself recognized, they simply indicate the relative yield position of brands according to a convention of analytical standards, but not actual conditions of smoke puffing or intake." (46)

A similar statement appeared in the 1981 U.S. Surgeon General's Report:

"The methods used in testing cigarettes by machine may not correspond to the way persons actually smoke. There is evidence to suggest

that cigarette yields measured by machine are very different from the yields that the consumer actually obtains by smoking the cigarette, due in part to the difference in patterns of smoking between testing machines and individual smokers." (47)

A recent study designed to compare the actual "tar," nicotine and CO intake of nearly 900 smokers and the FTC machine measurements of those substances illustrates the inaccuracies inherent in these measurements. The researchers reported that the FTC measurements were "poor predictors of relative intake of nicotine, CO, or tar," and observed that "the considerable variation of individual smoking behavior suggests that precise numerical rankings of cigarettes are not justified." (48) They concluded that their findings "reinforce previous reports and suggest that FTC measures have dubious meaning to consumers, except perhaps [for] a small fraction of smokers (2-3%) using very low yield cigarettes." (49)

The 1981 U.S. Surgeon General's Report addressed such difficulties in a series of research recommendations it made on this subject. As the Report notes, since smokers may smoke different cigarettes in different ways, "it is important to know how smokers consume each type of commercial cigarette" in order "to conduct meaningful assays of cigarette yields and of the biological activity of cigarette smoke." The Report asserts that "only when this

information is available can smoking-machines be designed to yield the most accurate estimate of human dose." (50)

Even before such scientific and technical uncertainties were expressed, questions had been raised regarding the necessity for establishing maximum constituent levels. A 1977 study, for example, suggested that the rationale for limiting "tar" and nicotine levels was lacking:

"Much money and effort are being spent on attempts to reduce tobacco smoking Some recent suggestions and developments include . . . cigarettes with low nicotine and tar yields, or cigarettes with high nicotine and low tar yields. The rationale for such measures is lacking since the role of nicotine and the mechanisms of pharmacologic reinforcement in tobacco smoking remain virtually unexplored." (51)

Similarly, a Belgium scientist looking back over the long-standing controversy surrounding the issue of smoking and health observed:

"Many scientists now claim that the reduction of the nicotine content in tobacco was not necessary at all and that all the laws and regulations which still attribute the principal risks of tobacco to nicotine have become virtually obsolete." (52)

There is no reliable scientific basis for imposing maximum tobacco smoke constituent levels in the EC. The claims of MCL proponents that low-yield cigarettes are preferable, from a public health standpoint, to other cigarettes are no more well

been determined to cause the alleged health risks of smoking. The imposition of maximum constituent levels gives governmental sanction to the "benefits" of low-yield cigarettes posited by the MCL advocates; the Member States would, if the proposal is adopted, mislead consumers by suggesting that a reliable scientific basis exists for switching to low-yield cigarettes. No such basis exists.

IV. THE PROPOSED EC COUNCIL DIRECTIVE WILL CREATE

founded than the claims that particular smoke constituents have

IV. THE PROPOSED EC COUNCIL DIRECTIVE WILL CREATE SIGNIFICANT POLITICAL AND ECONOMIC PROBLEMS FOR MEMBER STATES

As noted above, the proposed EC Council Directive calls for the prohibition of the sale of cigarettes with a "tar" yield of more than 15 mg by the end of 1992 and of more than 12 mg by the end of 1995. If adopted, the proposed Directive would create significant political and economic problems for Member States. Consumers would be forced to resort to "black markets" to obtain the products they desire. Producers would be forced to reduce output of current tobaccos, change the specifications of their products, or both, incurring substantial costs in the process. Governments will lose tax revenues and will be forced to incur additional law enforcement costs in implementing the contemplated prohibition.

The maximum "tar" limits in the proposed Directive would have a substantial impact on cigarettes currently sold in the

The maximum limit of 15 community. mg "tar" means that approximately 46 percent of all the cigarettes now sold in the Community would be banned after 1992. Certain countries would be hit harder than others. For example, the vast majority of cigarettes sold in Denmark, Greece, Spain and Portugal would fall The maximum limit of 12 mg "tar" means that 83 under the ban. percent of the cigarettes now sold would be ineligible for sale after 1995. From 75 percent to 100 percent of the sales in the Member States would be affected by the 12 mg limit. Such limits engender fundamental and unprecedented changes competitive structure of the Community cigarette market.

The proposed Directive would significantly affect all segments of the tobacco industry. It has been calculated that the jobs of 387,900 family and seasonal workers in Greece, France, Italy and Spain alone could be at risk. This is equivalent to over 100,000 full-time jobs and a loss of income totalling 334 million ECU. This represents over half of the jobs and incomes supported by the tobacco growing sectors of those countries. Significant losses would be incurred even if the shift in demand were less severe and tobacco growers found it possible to change to other types of leaf. In that situation, it has been calculated that the jobs of 143,000 family and seasonal workers in those same countries could be at risk. This is equivalent to over 37,000 full-time jobs and a loss of income totalling 125 million ECU. In

any case, it is likely that Greece would experience the heaviest losses of income and employment. The Spanish tobacco growing sector would also suffer disproportionately. Thus, the Directive would impose the greatest costs on two of the Community's Member States with relatively low incomes and restricted alternative employment opportunities.

The implementation of the proposed Directive would lead to a major decline in the demand for cigarettes manufactured largely from dark air-cured and Oriental tobaccos. If the market for most of these types of tobacco collapsed, and there was some decline in demand for European-grown light air-cured tobacco, between 65,000 to 70,000 small farmers and their families, a total of more than 250,000 people, could be forced to leave agriculture. Also affected would be thousands of seasonal workers. The farmers most at risk would those in the poorest regions of the Community: southern Italy, and central and southern Spain. If farmers forced out of agriculture had to seek employment in urban areas, incomes and employment opportunities in other sectors of their rural communities would also decline. The provision and quality of public and private services would likewise decline, and the cost of providing those services would increase. There is a possibility that farmers in France and Spain who grow dark air-cured and Oriental tobacco would switch to other varieties but not for those farmers in southern Italy and Greece. There are few alternatives to tobacco which would provide the level of cash income required to keep the small family farm as a viable unit. The likely effects of the proposed Directive on the more isolated marginal rural areas of the EC would appear to be in marked contrast to the declared purpose of the Commission to "avert serious economic and social disruption, and safeguard a pattern of rural developing in Europe, based on the promotion of the family business and balanced planning."

The Commission's suggestion of "reconversion to other crops" cannot be considered a solution to the problems faced by tobacco farmers if the Directive is adopted. The climatic conditions and the soil properties prevailing in the regions often concerned are inadequate for the cultivation of alternative crops suggested by the Commission (cotton, maize, fruit and vegetables) and would, therefore, only allow for products of inferior quality. The fact that many alternative crops are already in surplus in the Community should not be overlooked. The limits imposed under today's agricultural policy (quotas, stabilizers) effectively limit the possibilities reconversion. Any planned agricultural orientation toward the cultivation of tobacco varieties with low condensate yield could take years, perhaps decades, of careful research, development and breeding of new varieties meeting the new quality criteria (improved aroma and concomitant low condensate yields).

The Economic and Social Committee of the Council of European Communities noted such concerns in its opinion dated 7 July, 1988, when it conceded:

"[U]nless the reduction in tar limits is gradual, allowing for adjustments in EEC raw tobacco production and consumer requirements, there could be economic and social consequences owing to the fall in demand, the reduction in government tax revenue, job losses and increased imports of raw tobacco from third countries." (p. 2, para. 3.3)

comply with the Directive, additional production costs are likely, due to the probable replacement of national varieties by imported ones, especially for the production of national brands of cigarettes in the southern capital Mediterranean countries, and due to the need for different filters, and paper and tobacco blending. This will have some economic consequences in southern Mediterranean countries such as Greece." (p. 3, para. 3.9)

Thus, adoption of the proposed Directive will result in significant economic difficulties for many Member States: jobs and money will be lost, a segment of the agricultural community will be destroyed, and a way of life will be disrupted.

There would be other less quantifiable (but no less real) costs incurred in complying with the requirements of the proposed Directive. These costs include the consumers' restriction of

freedom of choice and the manufacturers' heavy costs in meeting the Directive's target goals.

The proposed Directive will make it attractive for people to engage in smuggling higher "tar" cigarettes across Community borders. It is impossible to predict the scale of such traffic, but a burgeoning "black market" in contraband high "tar" cigarettes may easily be envisioned. Cigarettes purchased on the "black market" would, of course, not be taxed by the Member States, causing a loss of revenue. Of more potential concern to the consumer, these contraband cigarettes would not be subject to quality-control "Black market" activity also carries with it law regulation. enforcement costs. Indeed, one can reasonably draw parallels between the proposed prohibition of high "tar" cigarettes in the Community and the ill-fated American experiment with the prohibition of alcoholic beverages; the latter imposed very high social costs on consumers and non-consumers of alcohol alike.

Those smokers who do not resort to contraband cigarettes may choose to roll their own cigarettes, with or without filters. This result, as with use of contraband cigarettes, places Community—manufactured cigarettes at a considerable competitive disadvantage, since no maximum yield can be set for handrolled cigarettes. Smokers may also attempt to frustrate the MCL legislation by using conforming cigarettes improperly. For example, smokers may break

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the filters off of filtered cigarettes. Smoking cigarettes in this manner would vitiate any value that may have existed for the yield figures placed on the packets. Another problem occurred in Sweden, which required that certain constituent levels be included in the warning labels on cigarette packets: young smokers use the declaration to pick out the "strongest" cigarettes.

The proposed Directive also will result in an excessive intervention into the proprietary positions of individual producers. The excessive nature of the ban is especially evident when viewed against the scientific uncertainty of the alleged health risks arising from the condensate yields of cigarettes at particular levels. Reliable scientific data on the alleged risk of a condensate yield of 15 mg or 12 mg as opposed to a higher condensate yield are not available.

It is standing case law of the European Court that the Community legislator has to observe the principal of proportionality according to which legislative measures must be appropriate to the Community objective pursued and must not entail excessive burdens for all those concerned. In view of this principle, it is essential to note that a ban on up to 83 percent of present Community production of cigarettes can only be put into effect with the help of imports of raw tobacco from third countries. This implies that the Community will have to export or destroy

its surplus in tobacco varieties yielding condensate yields in excess of the Directive ceiling.

A significant reduction of the weighted condensate average has been reached in several Member States on the basis of voluntary agreements. Legislative health measures are per se excessive in situations where voluntary measures have proven sufficient to reach the stated objective.

The necessity of "tar" ceilings is further refuted by the commercial evolution of the markets in which average "tar" yields have fallen considerably since the early 1970's in response to consumer demand. Consumers are fully capable of making reasoned choices based on readily available product information. Manufacturers have in turn responded to shifts in consumer preference, adjusting their products to meet current tastes, preferences, and income levels. The proposed ban will force upon consumers cigarettes about which they have little information -contraband cigarettes illegally imported and purchased on the "black market," hand-rolled cigarettes, and filter cigarettes from which the filters have been removed. Differences in consumer tastes and preferences between Member States would complicate any efforts to establish a Community-wide acceptable maximum.

The prohibition of cigarettes above a certain "tar" level raises fundamental questions about the role of the Community in determining the rights of consumers to have access to historically lawful products. Such action would be contrary to the principal of consumer sovereignty in that it would limit, rather than expand, consumer choice in the marketplace. EC consumer law is intended to emancipate the consumer by assisting him to become well-informed, not to reduce the range of products from which he may choose.

The manufacture of low to medium "tar" cigarettes is a highly sophisticated process. The acquisition of suitable machinery requires significant investment, as well as extensive restructuring and re-education of labor. Therefore, introduction of a "tar" ceiling will result in the economic obsolescence of existing investment, notably within the monopolies and in Greece. The competitiveness of these companies will also be jeopardized by their likely inability to introduce the new technology required to meet such a limit within reasonable time limits. Only gradual, consumer-led reductions are feasible if major disruption is to be avoided.

V. CONCLUSION

Numerous claims have been made about the relationship between cigarette smoke constituents and the health of the smoker.

However, such claims are just that -- claims which are not supported by reliable scientific proof. After years of study, no scientific relationship has been established between "tar," carbon monoxide, nicotine and adverse health effects. The imposition of arbitrary maximum permissible levels of such substances is unwarranted because the scientific support for claimed risk reduction is open to question, and the relevance of maximum required levels as determined by machines to human smoking behavior is unclear and equivocal. Such legislation, moreover, is misleading to the smoker. It suggests that a reliable scientific basis exists for switching to low-yield cigarettes. No such basis exists.

The imposition of maximum constituent levels in the European Community will result in significant economic and political problems for Member States. The agricultural and industrial sectors of the economies of many Member States will be disrupted by the forced changes in tobacco production and cigarette manufacture. Jobs will be lost, governmental revenues will decrease, and any competitive advantage for Community-manufactured cigarettes will be severely diminished. Consumers of cigarettes will be denied the free choice of a wide range of well-made cigarettes. They will be forced to purchase contraband cigarettes on the "black market," hand-roll their own cigarettes, or otherwise satisfy their desire for an historically available product. Thus,

the adoption of the proposed Directive makes neither scientific sense nor good social and economic policy.

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